

# Consent Policy Design Group

## Meeting Minutes

MEETING DATE	MEETING TIME	Location
September 24, 2019	1:00PM – 2:30PM	<b>Join Zoom Meeting:</b> <a href="https://zoom.us/j/269726549">https://zoom.us/j/269726549</a> <b>Dial:</b> +1 646 876 9923 US <b>Meeting ID:</b> 269 726 549

DESIGN GROUP MEMBERS					
Stacy Beck, RN, BSN	X	Susan Israel, MD	X	Nic Scibelli, MSW	X
Pat Checko, DrPH	X	Rob Rioux, MA		Rachel Rudnick, JD	
Carrie Grey, MSIA					

SUPPORTING LEADERSHIP					
Allan Hackney, OHS		Carol Robinson, CedarBridge	X	Sheetal Shah, CedarBridge	X
Tina Kumar, OHS		Michael Matthews, CedarBridge	X	Tim Pletcher, Velatura	
Sean Fogarty, OHS	X	Chris Robinson, CedarBridge	X	Lisa Moon, Velatura	

Minutes			
	Topic	Responsible Party	Time
1.	<b>Welcome and Overview</b>	Allan Hackney	1:00 PM
	Michael Matthews welcomed the group and provided an overview of the agenda.		
2.	<b>Public Comment</b>	Attendees	1:02 PM
	There was no public comment		
3.	<b>Review and Approval of Meeting Minutes</b>	Attendees	1:05 PM
	Pat Checko created the motion to approve the meeting minutes from September 17, 2019. Susan Israel seconded the motion and it was approved without objections or abstentions.		
4.	<b>Discussion of Guiding Principles</b>	Attendees	1:10 PM
	<p>Michael gave an overview of the guiding principles exercise and explained that we will be discussing each principle and reviewing how they were scored by the Design Group members who responded. Michael said that principles 1, 9, 15, and 18 appeared to have consensus for acceptance, or acceptance with changes. Principles number 10 and 11 received comments that they were more relevant to HIPAA, and perhaps should be removed. Michael said we will start with these 6 principles.</p> <p><b><u>Principle #1:</u></b></p> <p>Susan Israel requested that her comments regarding this principle be included in the minutes in their entirety:</p> <p><i>The public needs to be informed whether CT is an opt-out state for transparency and in order for the “unambiguous information about health sharing choices,” name the groups (who) will be seeing their data (identified or unidentified) and where the data would be sent and stored temporarily or permanently. It must be stated for which data the patients can exercise consent vs what are automatically sent by their providers by virtue of receiving medical care:</i></p> <ol style="list-style-type: none"> <li>1) <i>identify and care mapping data</i></li> <li>2) <i>identity quality control</i></li> <li>3) <i>clinical care summaries with diagnoses and medications</i></li> </ol>		

- 4) *empanelment*
- 5) *quality data measurement output*
- 6) *public health beyond communicable diseases*
- 7) *opioid medication that includes psychiatric drugs which are also controlled substances*
- 8) *outpatient and inpatient discharge summaries*
- 9) *identified tumor registry*
- 10) *lab and imaging data*
- 11) *individual electronic health record longitudinal data*
- 12) *Surescripts data (from which there is an opt-out?)*

*Obviously, there is the tension of patient rights to opt-out of an electronic health information exchange for their mandated data to go to OHS/CT. But the removal of patient right of consent for the sharing of their data for TPO which includes oversight was removed by HHS in 2003 without Congressional approval. CT taking so much private medical data (including the APCD) and the HIPAA rules certainly stretch what the government is “allowed” to do under the 4<sup>th</sup> amendment.*

Susan explained that she thinks this is an important topic for the public to be aware of. She wants patients to understand which use cases will provide them with a consent option, versus which use cases will fall under HIPAA TPO. Another point Susan wanted to discuss was the idea of opting out of the HIE. Susan said she wants to revisit this issue in the context of what level of consent will be provided to patients and consumers. Susan did not want to commit to accepting any principles until she was more comfortable with the transparency to the public.

Michael thanked Susan for her comments. He added that Rachel Rudnick has also been requesting additional details on the use cases and the HIE. Michael said that from the beginning, we have explained that we may not achieve unanimous endorsement of certain principles, and it will be important to represent the other viewpoints within the group. Michael asked Susan if there is a statement that can be included to summarize her comments on this topic for inclusion in a final report. Susan said this would be acceptable, if the group agrees. She said if anybody has comments about whether or not they agree with this point, she would appreciate people’s feedback at the end of the meeting.

Pat said the concept of “opt-in versus opt-out” and does not think that this is totally understood by the topic and should be discussed in more detail. Michael said that the opt-in and opt-out language was useful in the early days of HIEs when there was only one type of exchange, which was query for documents. The idea of having a blanket statement to apply to all use cases no longer is a viable approach for a consent model within HIEs. Carol Robinson agreed with this statement. Carol said that in recent years, a number of technical approaches have been researched, including data segmentation for privacy (DS4P) and Consent to Share from SAMHSA. Progress is being made.

Michael said he believes that principle #1 is in alignment with Susan’s comments. Rachel made the point that the portion of the principle related to translational services should not be included, as it may be more appropriate elsewhere.

Michael asked if the revised principle, “Consent policies require patients be provided clear and unambiguous information about health information sharing under applicable State and Federal law.” Susan said she has some concerns with this language, such as this will block patients from having more meaningful consent. Susan said that if means there will be alignment with HIPAA, then she is concerned because she does not believe HIPAA goes far enough to protect patient data. Michael asked if this will

apply to all of the principles. Susan said she does not want to slow down the discussion, and we can move on now that it has been stated. Susan said she does not want to score this principle at this time.

Susan asked for more information on TECCA and the concept of meaningful choice. Michael said that TECCA and the information blocking rule were both part of 21<sup>st</sup> Century Cures Act. Michael said the impacts are not clear today, but it will certainly be part of the interoperability space in Connecticut in the future. Susan asked if Michael would be willing to talk to her another time to provide more information. Michael agreed.

Michael asked if there were any other objections to the proposed language. Nic Scibelli, Pat Checko, and Stacy Beck said they do not have any objections. Pat asked what happened to the language regarding translational services and Michael explained that he thinks it will fit more appropriately under a different principle, such as principle 2.

#### **Principle #9:**

Michael provided an overview of this principle and the responses that were received. Michael asked Susan if she is comfortable with this principle. Susan said that she is willing to accept this principle.

Carol said there was some internal discussions around this principle. Carol said that there were some who feel there should be some mention of the down-stream notification of consent withdrawal to applicable providers. Nic Scibelli said that Carol's explanation sounds more like what the policies will be, whereas all the principle is stating is that there is a need for the policy itself. Carol said this may be sufficient, but she is wondering if we can address the concern that was raised by adding some language. Susan said she thinks this is important and some language should be added. Nic said that this could be too technical and too detail oriented. Carol said that perhaps we should include a statement about consent authorization, in addition to consent, in the principle. Pat added that we should replace the word "after" with "if".

Michael asked the group if they accept the revised principles stating, "Consent policies should explain what will happen to the patient's data and previously provided authorization, if consent is withdrawn."

Pat Checko, Nic Scibelli, Stacy Beck, and Susan Israel accepted this language.

Michael said we will reach out to the other Design Group members, including Rachel, to make sure they accept, or still accept, this principle following the revisions.

#### **Principle #15:**

Michael provided an overview of this principle and the responses that were received. Susan said that she also accepts this principle as written. This principle is accepted as written by Stacy Beck, Nic Scibelli, Rachel Rudnick (via writing), Pat Checko, and Susan Israel.

#### **Principle #18:**

Michael provided an overview of this principle and the responses that were received. Susan Israel said that she also accepts this principle as written. This principle is accepted as written by Stacy Beck, Nic Scibelli, Rachel Rudnick (via writing), Pat Checko, and Susan Israel.

#### **Principle #10:**

Michael provided an overview of this principle and the responses that were received. Michael explained that this principle is a HIPAA privacy requirement, not a consent policy requirement. Michael suggested

if we should delete this principle. Nic Scibelli agrees that this could be deleted and said this is already something that his organization is required to do.

Pat Checko said that she was unaware that third-party vendors and contractors could use the data for undisclosed purposes. Nic said that they typically sign BAAs with organizations that need access to data, such as EHR vendors, and these BAAs typically describe how the data can and cannot be used, as well rules around disclosing that data, protections, breach notifications, indemnity, liability, etc. Nic said that this is standard practice for organizations that need to contract with third-party vendors. Pat asked for an example of an undisclosed purpose. Nic said he is not sure what would be included here. Pat said she is concerned that this is muddying the waters. Carol explained that there are state and regional HIEs that allow de-identified data sets to be provided, similar to the APCD, that would be used for public health research, for example.

Susan said she thinks this should be left in the principles, because she wants people to understand how their data is used. Susan said she would accept this principle. Pat said she also accepts this principle.

Michael asked Nic if he agrees that this principle does not add anything in terms of consent policy development and if he can provide a few more sentences. Nic said that these do not change anything, because they are already required activities. Nic said that perhaps there needs to be an educational component, as opposed to this principle, in line with Susan's comments. Nic is curious on Rachel's perspective on these items, and if there would be any conflict or issue with including this language.

Michael agreed and said he does not want to push the group to a decision, but these items may not be relevant. Michael asked for Pat's perspective. Pat said that if this is part of HIPAA, then it may be superfluous, but perhaps there needs to be education on what HIPAA allows. Pat said that as a consumer, she would want to know that these things are required. She is fine either with inclusion or removal. Michael said that since these items are HIPAA related, perhaps we should double-check with Rachel and defer to her judgement. Pat, Stacy, and Nic agreed with this approach. Susan said she wishes this item was more specific.

Michael explained that principles 10 and 11 were adapted, with permission, from the CARIN Alliance.

Michael said that the conversation on this principle applied to principle 11 as well. The group agreed with this statement.

#### **Principle #2:**

Michael provided an overview of this principle and the responses that were received. Michael said that the concern on this item was that it should not be dependent on funding availability. Michael asked if there is support for acceptance, if the statement on funding dependency is removed.

Pat Checko said that she agrees and accepts the principle as modified.

#### **Principle #3:**

Michael provided an overview of this principle and the responses that were received. Based on comment received, Michael explained that HIA is the business name for the HIE entity, which is a private not-for-profit organization. Michael said this exercise will be to develop some perspectives and recommendations that will inform HIA as they go about managing and operating the HIE and that there will be a close working relationship between HIA and the Health IT Advisory Council.

Michael said that in terms of consent and the dissemination of consent policies, it could be argued that OHS and HIA would be involved in the communication of the policies. Therefore, for this principle, Michael suggests that OHS could be added to this principle as having a to-be-defined role in terms of

communication. Michael said that the issue in this case is the development of policies around use case documentation. Nic Scibelli said that he does not feel the need to include OHS in this principle.

Pat said that she is still trying to make sense of the governance of the HIA. Pat asked if HIA is a private organization or a quasi-governmental entity. Michael said it is a private not-for-profit organization that has state representation on its board and will be closely involved with the state. Pat said she would be more comfortable by claiming a role for OHS because she is cautious about HIA being autonomous. Pat said she thinks the Health IT Advisory Council should be included as having a role in principle 4.

Susan Israel asked if HIA would decide the consent policies by themselves. Michael said this would be part of HIA's overall governance and fiduciary responsibilities and they need to administer their own policies. The exercise we are doing with this group in developing guiding principles is to inform their policy development process. Michael said that this group could make a recommendation that any such policies should be reviewed and have a comment period from the Health IT Advisory Council, then that is up to this group's discretion. This could be included in a guiding principle. If the Health IT Advisory Council wanted to advocate for legislation for a mandated consent policy, this would take us down an entirely different path. In the current environment, HIA would govern and manage the HIE and would be responsible for policy development. The Health IT Advisory Council would inform that policy. Nic said that it is confusing in terms of scope and asked if we are just talking about consent policies. He would not be in agreement that a private non-profit should have every policy reviewed and commented on, in addition to the already purposed and approved regulatory governing structures for that non-profit. In regard to number 3, we are not talking about policy development. In principle four, we get into the consent policy review, and there could be a role for the Advisory Council.

Michael asked if everyone is okay with number 3 if we add OHS. Susan said that a private organization should not unilaterally determine policies on their own. Susan said there should be as much public oversight as possible. Susan said she is fine with number 3 if it is only relevant to education. Michael clarified that number 3 is only about the dissemination of information. Nic said he is not okay with number 3 and he does not see why OHS needs to be involved with principle 3. Nic said this seems redundant and overly bureaucratic. Michael said this would pertain more to support, rather than oversight. Nic said he would be okay with a support role. Pat said there is a huge difference between distributing the resources and supporting the development of the resources. Michael said that his opinion is that it is the responsibility of HIA to develop the resources, and then the dissemination could be supported by their partners.

Carol Robinson asked the question of whether this is a consent policy for just HIA, or if this is a consent policy for other organizations exchanging data as part of the network-of-network approach. She believes this will change the responsible. Michael said that his understanding of the exercise is that we are informing the consent policies for HIA, and not for the state more broadly. Carol said this question was raised internally, and she wants this to be transparent and defensible. Michael said we will make note of this and follow-up in a subsequent meeting. Sean Fogarty said that OHS wants to empower HIA to be a neutral and trusted entity. Sean thanked everyone for their thoughtful comments.

Pat Checko said that consumers and people in general have enough distrust in private entities, like insurance companies, to assume that we can create this private non-profit entity with no oversight. Pat said that as we talk about this larger question, she would like to raise this point for discussion. Sabina Sitaru said that the HIE entity will be governed by the participating organizations through the Operational Advisory Committee. HIA will be advised by the Health IT Advisory Council through OHS. Susan said that she is concerned that this will bypass the legislature with its appointments and that we are far from the consumer being able to have input in terms of how their data will be handled. Susan

suggested there be public forums. Sabina thanked Susan for her comments and will be sure this point is well noted.

**Principle #4:**

Michael said it is his observation that some of the discussion is not focused on policy development, or consent policies, as they are focused on the governance and oversight and relationships of the Advisory Council, the state, the statutes, and the enabling legislation of the HIE. Michael worries we are losing our focus and wants to reel the group back in. Michael said that the concept on principle 4 was that a use case should not be developed and deployed without a consideration for the attached consent policies. Michael said that the intent was to have consent policy implications reviewed and considered along with the development of each use case.

Susan said that this is a good point, but she would like to have a wider approach in terms of use case development. Susan would like to have the Advisory Council involved, as well as public transparency. She thinks principle 4 should be broader. Michael said that if we remove the words “by HIA, inc.” and make this principle more generic, would this be acceptable? Pat said that this is simple and straightforward, and she would agree with this point.

<b>5.</b>	<b>Wrap Up and Meeting Adjournment</b>	<b>Michael Matthews</b>	<b>2:25 PM</b>
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Michael said he thinks it will take another full meeting to get through the remainder of these principles. We will re-publish the guidelines that reflect the Design Group’s input from today’s meeting. The next meeting will take place on October 15 at 1pm ET, and Michael thinks we will need another meeting after this. At the next meeting we will determine the format of the final report in order to best represent all of the opinions of the group. Design Group members agreed with this point.